

## **PREMARKET NOTIFICATION**

SYNTHETICALLY PRODUCED (-)-HYDROXYCITRIC ACID

SUBMITTED BY

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UPPER CLARE STREET,  
LIMERICK,  
IRELAND

MAY 2005

**COOLWATER TRIM™**  
**75 Day Pre-Market Notification**

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**NAME AND ADDRESS OF DISTRIBUTOR AND CURRENT  
MANUFACTURER**

Distributor:  
Broderick & Tourville  
26 Washington Street  
3rd Floor  
Morristown  
NJ 07960

GMP Manufacturer:  
Mingshen Chem Pacific Ltd.  
741 Moganshan Road  
Hangzhou  
China

**1. GMP BOTTLER/PACKAGER**

Shannon Minerals Limited  
Upper Clare Street,  
Limerick ,  
Ireland.

Tel: + 353 61 418068  
Fax + 353 61 418179  
E-Mail [brendanomara@shannonminerals.ie](mailto:brendanomara@shannonminerals.ie) or [willie@shannonminerals.ie](mailto:willie@shannonminerals.ie)

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**2. NAME AND IDENTITY OF NEW DIETARY INGREDIENT**

Chemical Name: (2S,3S) –2- Hydroxycitric Acid

Other Name: (-) - Hydroxycitric Acid

Common Name (-) HCA, (-) -Hydroxycitrate

(See also (-) – Hydroxycitric Acid – The principal Acid in the fruits of *Garcinia Cambogia* Desr., Lewis and Neelakantan, Central Food Technological Research Institute, Mysore, India, March 1964) – (Appendix A)

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**3. DESCRIPTION OF THE PRODUCTS CONTAINING  
SYNTHETICALLY PRODUCED(-)-HYDROXYCITRIC ACID**

500ml solution containing 1167 mg of Tripotassium Hydroxycitrate delivering 700mg (-) - HCA. To be sold in individual bottles containing 500 ml of solution

Other Ingredients: Water, Citric Acid, APPETRIM™ synthetic (-) - Hydroxycitrate, Natural Flavour, Aspartame, Sodium Benzoate, Potassium Sorbate as preservatives and Asculfame Potassium.

To be branded as *Coolwater Trim™* and sold in a variety of flavours.

**CONDITIONS OF USE:**

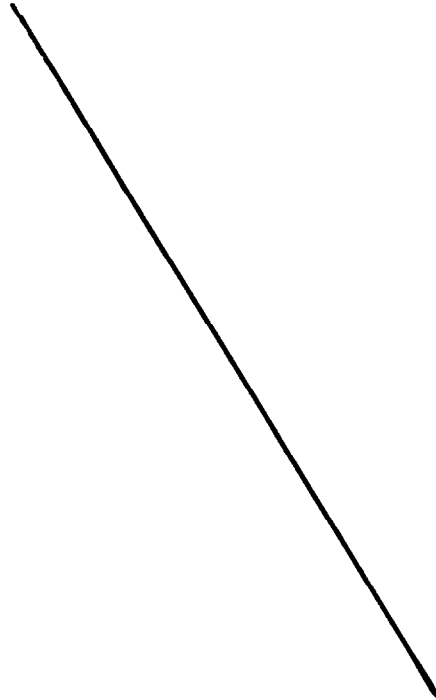
Use as a dietary supplement consuming one bottle no more than four times daily. Not recommended for use by young children or by pregnant or lactating women. The label will provide the phenylketonurics cautionary statement (21 CFR § 172.804(d)(2)).

**PROCESSING AND METHOD OF MANUFACTURING**

Information on production of the APPETRIM™ synthetic (-) - Hydroxycitrate, the source of the HCA dietary ingredient, including quality checks, tests, and specifications to ensure its identity, is set forth on the following pages. Similarly, information on the *Coolwater Trim™* Dietary Supplement, including its processing and quality control and other procedures in place to ensure its safety, is set forth on the following pages. Pages containing trade secrets or confidential commercial information believed to be exempt from disclosure when this notification is published at the Dockets Branch are marked "CONFIDENTIAL"

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ADDITIONAL INFORMATION CONCERNING APPETRIM™  
(TRIPOTASSIUM HYDROXYCITRATE)



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PROCESSING AND METHOD OF MANUFACTURING Appetrim®

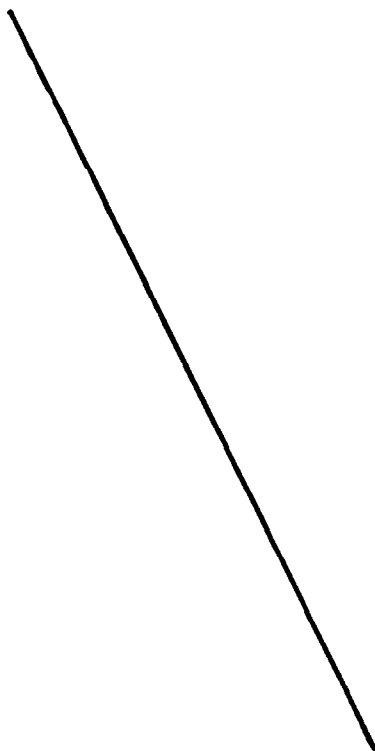


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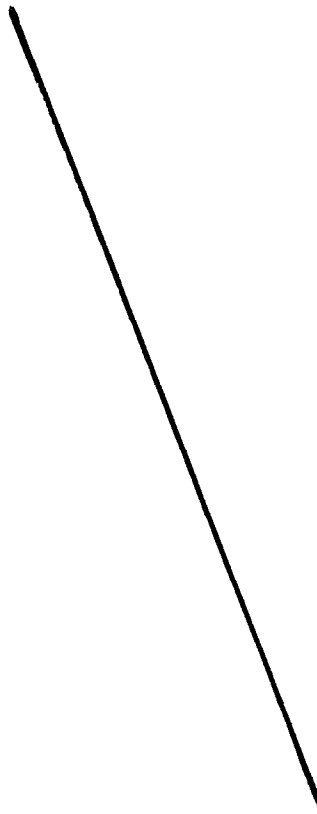
*PRODUCTION CHART*

**Appetrim® Synthetically produced (-)-HCA- K**



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**Certificate Of Analysis**

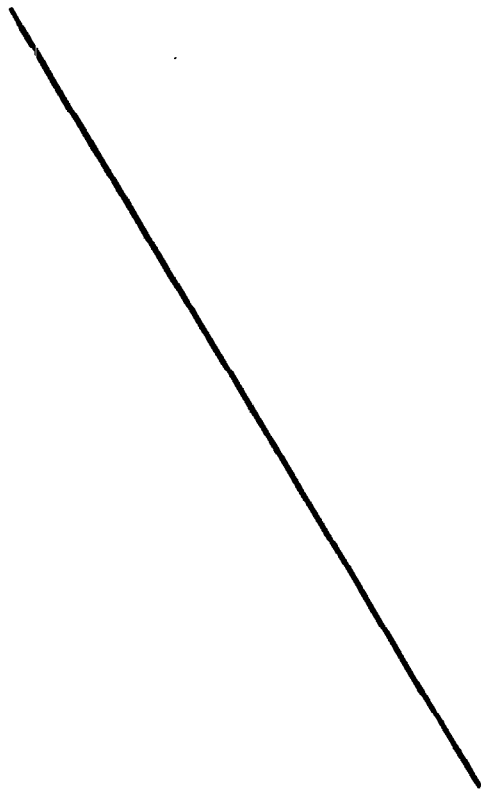


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SPECIFICATION SHEET



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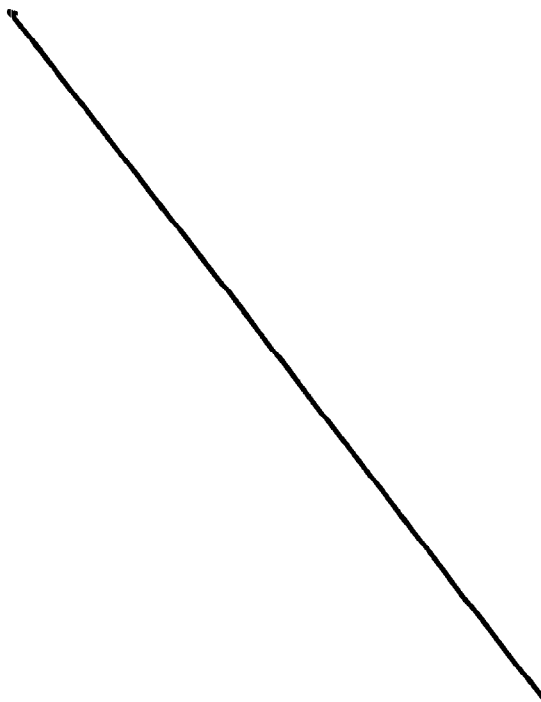
E info@shannonminerals.ie

W www.shannonminerals.ie

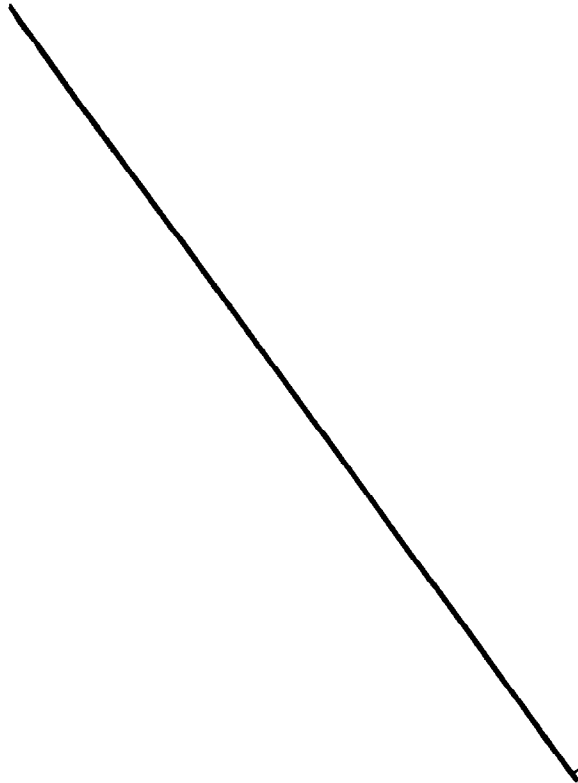
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# HPLC METHOD FOR ESTIMATION OF K-HCA



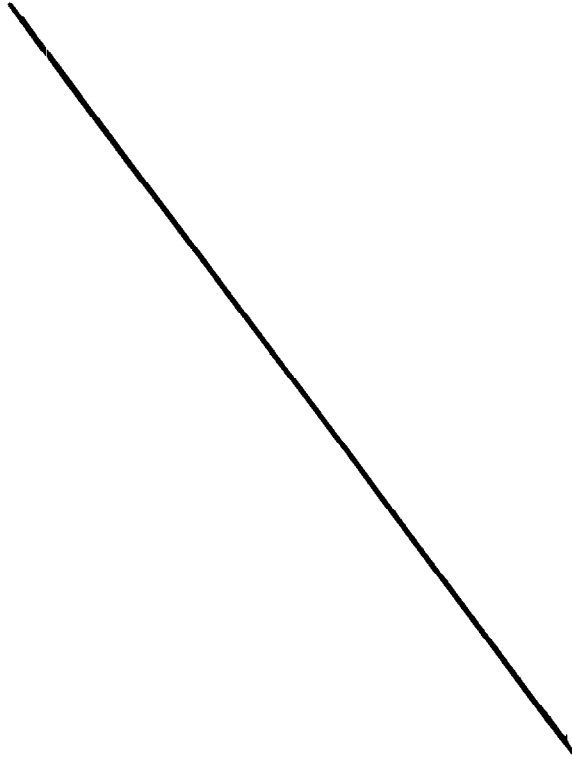
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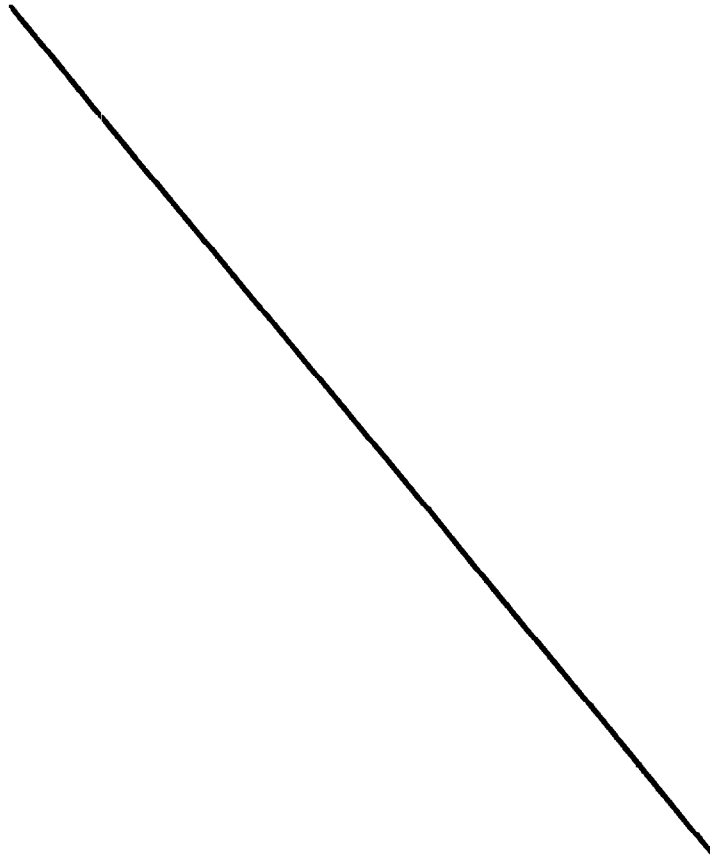


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QUALITY AND MANUFACTURING PROCESS FOR COOLWATER TRIM™

Overall Process Flow Diagram



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